



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,114	05/18/2001	Hyo Jeong Hong	118.13-US-WO	5095

22462 7590 06/27/2005

GATES & COOPER LLP  
HOWARD HUGHES CENTER  
6701 CENTER DRIVE WEST, SUITE 1050  
LOS ANGELES, CA 90045

EXAMINER

WANG, LOUISE Z

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/856,114	<b>Applicant(s)</b> HONG ET AL.	
	<b>Examiner</b> Louise Wang	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 16-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

S. a o

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 16 and 29, drawn to humanized antibody specific for HBV surface antigen pre-S1, comprising a humanized heavy chain variable region of SEQ ID NO: 20.

Group II, claims 17 and 29, drawn to a humanized antibody specific for HBV surface antigen pre-S1, comprising a humanized heavy chain variable region of SEQ ID NO: 21.

Group III, claims 18 and 29, drawn to a humanized antibody specific for HBV surface antigen pre-S1, comprising a humanized heavy chain variable region of SEQ ID NO: 21 with at least one amino acid substitution.

Group IV, claims 19 and 29, drawn to a humanized antibody specific for HBV surface antigen pre-S1, comprising a humanized light chain variable region of SEQ ID NO: 23.

Group V, claims 20,21,24-26, drawn to a gene encoding a humanized heavy chain comprising an amino acid sequence of SEQ ID NO: 20.

Group VI, claims 20, 22,24-26, drawn to a gene encoding a humanized heavy chain comprising an amino acid sequence of SEQ ID NO: 21.

Group VII, claims 20, 24-26, drawn to a gene encoding a humanized heavy chain comprising an amino acid sequence of SEQ ID NO: 21 with at least one amino acid substitution.

Group VIII, claims 23,27,28, drawn to a gene encoding a humanized light chain containing an amino acid sequence of SEQ ID NO: 23.

Group IX, claim 30, drawn to a method of prevention or treatment of HBV.

Art Unit: 1648

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature among these inventions is the humanized antibody specific for HBV surface antigen. Such an antibody is disclosed in Choi et al. (Hybridoma 17: 535-540) and Ryu et al. (Human Antibodies Hybridomas 7: 113-122 of record in the IDS of April 2002). The Groups therefore share no common special technical feature over the prior art.

### ***Species***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Groups III and VII above, the Applicant is required to elect one of the following species: embodiments of the claimed inventions wherein the amino acid substitution is:

- (a) Lys<sup>12</sup> → Val<sup>12</sup> (claims 18, 29, and 20, 24-26);
- (b) Thr<sup>28</sup> → Ala<sup>28</sup> (claims 18, 29, and 20, 24-26);
- (c) Thr<sup>30</sup> → Ser<sup>30</sup> (claims 18, 29, and 20, 24-26);
- (d) Met<sup>48</sup> → Ile<sup>48</sup> (claims 18, 29, and 20, 24-26);
- (e) Arg<sup>67</sup> → Lys<sup>67</sup> (claims 18, 29, and 20, 24-26);
- (f) Val<sup>68</sup> → Ala<sup>68</sup> (claims 18, 29, and 20, 24-26);
- (g) Met<sup>70</sup> → Leu<sup>70</sup> (claims 18, 29, and 20, 24-26);
- (h) Val<sup>79</sup> → Ala<sup>79</sup> (claims 18, 29, and 20, 24-26);
- (i) Tyr<sup>95</sup> → Phe<sup>95</sup> (claims 18, 29, and 20, 24-26).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim is generic: 18 and 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the same reason as indicated with Groups I-VIII above. These claims fail to disclose a common special technical feature over the prior art.

### ***Conclusion***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

It is here noted that some of the restriction requirements made above fall within the scope of PTO linking claim practice. In accordance with this practice as described

Art Unit: 1648


in MPEP §809.03, linking claims will be considered with the elected inventions. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise Wang  
June 10, 2005

  
JAMES HOUSEL 6/24/05  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600